IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

Shawver, et al.,

Plaintiffs,

v.

Zimmer Biomet Spine, Inc.,

Defendant.

Case No. 3:24-cv-00454-JGC

ORDER

This is a claim for damages resulting from an allegedly defective and unreasonably dangerous medical device.

Defendant is Zimmer Biomet Spine, Inc. ("ZB Spine"). ZB Spine produces a cervical disk replacement implant called the Mobi-C. (Doc. 7-1, PgID. 65).

Plaintiffs are Phebe and Allison Shawver. In June 2021, Phebe Shawver underwent cervical disk replacement surgery using ZB Spine's Mobi-C implant. (*Id.* at PgID. 66–67). She alleges that the subsequent failure of the implant caused her serious and persistent bodily harm. (*Id.* at PgID. 67). This included the need for further surgery and additional related medical expenses plus other damages. (*Id.* at PgID. 67, 71).

Plaintiffs filed suit in the Wood County Court of Common Pleas. (Doc. 1-1). Defendant then removed the case to this court based on diversity of citizenship under 28 U.S.C. § 1332. (Doc. 1, PgID. 2). Pending is Defendant's Federal Rule of Civil Procedure 12(b)(6) motion to dismiss Plaintiffs' complaint. (Doc. 9). Plaintiffs responded, (Doc. 10), and Defendant filed a reply, (Doc. 12).

For the reasons that follow, I grant Defendant's motion. I also grant Plaintiffs leave to file an amended complaint within three weeks of the issuance of this order.

Background

Plaintiffs live in Bowling Green in Wood County, Ohio. (Doc. 7-1, PgID. 66). In June 2021, Plaintiff Phebe Shawver underwent cervical disk replacement surgery at Wood County Hospital. (*Id.*). That surgery implanted in Plaintiff's spine Defendant's Mobi-C medical device. (*See id.* at PgID. 65–67). The Mobi-C is "a cervical disc prosthesis system used for reconstructing a cervical disc [and which] is designed to mimic the function of a natural intervertebral disc, preserving motion in the treated segment of the spine while providing stability." (*Id.* at PgID. 65).

After the surgery, Plaintiff suffered increasing numbness, tingling, and weakness "with cord compression and severe myelopathy symptoms." (*Id.* at PgID. 67). Subsequent imaging indicated a problem at the site of the surgery. (*Id.*).

On September 28, 2023, Plaintiff underwent a second surgery to address the issue. (*Id.*). This surgery revealed that part of the Mobi-C implant had failed. (*Id.*).

The Food and Drug Administration (FDA) regulates the Mobi-C implant as a Class III medical device.[1] (*See* Doc. 9-1 (FDA's Mobi-C premarket approval letter filed as Exhibit 1 to

[1] As I previously explained in *Warstler v. Medtronic, Inc.*, 238 F. Supp. 3d 978, 982 n.1 (N.D. Ohio 2017):

> The [Medical Device Amendments of 1976 (MDA)] impose[] different levels of federal oversight depending on the risks presented by a particular device. [21 U.S.C.] § 360c(a)(1)(A)–(C). Class I devices receive the lowest level of oversight: "general controls." § 360c(a)(1)(A). Class II devices, in addition to "general controls," are subject to "special controls." § 360c(a)(1)(B). Class III devices . . . receive the most federal oversight.
>
> A device receives Class III designation "if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness," *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008), and the device is "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human

Defendant's Motion to Dismiss)).[2] Class III medical devices must receive premarket approval (PMA) from the FDA "to provide reasonable assurance of [the device's] safety and effectiveness." 21 U.S.C. § 360c(a)(1)(C). The PMA process is a "rigorous regime" of federal regulation. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008); *see, e.g.*, 21 U.S.C. § 360e(c)(1) (requiring as part of a PMA application, among other things, "full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective; a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device; . . . [and] specimens of the labeling proposed to be used for such device"). In assessing the safety and effectiveness of a Class III medical device for PMA, one of

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health" or "presents a potential unreasonable risk of illness or injury." § 360c(a)(1)(C)(ii).

[2] Generally, I cannot consider "matters outside the pleadings" in deciding a Rule 12(b)(6) motion to dismiss unless I treat the motion "as one for summary judgment under Rule 56." Fed. R. Civ. P. 12(d). I decline to do so here. Nevertheless, I may, "in undertaking a 12(b)(6) analysis, take judicial notice of 'matters of public record, orders, items appearing in the record of the case, and exhibits attached to the complaint.'" *Elec. Merch. Sys. LLC v. Gaal*, 58 F.4th 877, 883 (6th Cir. 2023) (quoting *Golf Vill. N., LLC v. City of Powell*, 14 F.4th 611, 617 (6th Cir. 2021)).

The FDA's premarket approval letters and related supplements for Defendant's Mobi-C implant are publicly available on the FDA's website. Premarket Approval Database, U.S. Food & Drug Admin., https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm. This material is also the sort of public record that courts routinely consider in cases like this one. *E.g.*, *Aaron v. Medtronic, Inc.*, 209 F. Supp. 3d 994, 1014 (S.D. Ohio 2016) ("This Court may take judicial notice of [the product]'s receipt of [premarket approval] from the FDA . . . ."). I therefore take judicial notice of such approval here.

I note that as an exhibit to their opposition to Defendant's motion, Plaintiffs filed a premarket approval letter for the Mobi-C implant dated August 7, 2013. (Doc. 10-1, PgID. 156). Defendant, however, filed as an exhibit to its motion a Mobi-C implant premarket approval letter dated August 23, 2013. (Doc. 9-1, PgID. 114). In addition to the letters' differing dates, other differences between the two exhibits are apparent. For example, Defendant's letter states that the implant is "for reconstruction of the disc from C3-C7 following discectomy at two contiguous levels." (*Id.*). Plaintiffs' letter, however, states the implant is "for reconstruction of the disc at one level from C3-C7 following single-level discectomy." (Doc. 10-1, PgID. 156).

No party explains the discrepancies between these letters. However, Plaintiffs in their opposition briefing characterize the August 7th letter as an "initial" premarket approval letter. (Doc. 10, PgID. 137). Plaintiffs then devote a portion of their briefing to describing some of the regulatory requirements that the August 23rd letter establishes. (*Id.* at PgID. 140–41). And Plaintiffs next argue that my consideration of apparently yet another premarket approval letter, perhaps misdated to August 13, 2013, would convert Defendant's motion to dismiss into a motion for summary judgment. (*Id.* at PgID. 143).

Nevertheless, this confusion surrounding the specifics of the Mobi-C implant's premarket approval is irrelevant to my decision here. Neither party disputes the critical fact that, whatever the specific terms of the FDA's premarket approval, the Mobi-C implant is a Class III medical device that received such approval. It is that fact alone of which I take judicial notice here.

the factors the FDA must consider is "any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2)(C).

A Class III medical device to which the FDA grants PMA is subject to continuing FDA oversight. 21 U.S.C. § 360e(d)(5). Any changes to the device require a "supplemental application" that the FDA reevaluates for safety and effectiveness. 21 U.S.C. § 360e(d)(5)(A)(i), (B)(i). The FDA also imposes a variety of continuing reporting obligations on device manufacturers. *E.g.*, 21 U.S.C. § 360i(a); 21 C.F.R. § 803.50(a) (requiring device manufacturers to report any instances in which their device or its malfunction caused or might likely cause death or serious injury); 21 C.F.R. § 814.84(b)(2)(i) (requiring PMA holders to provide, among other things, updates regarding "[u]npublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices").

Plaintiffs bring nine claims stemming from the harm Plaintiff Phebe Shawver allegedly suffered when her Mobi-C spinal implant failed. Plaintiffs ground five of these claims in the Ohio Products Liability Act (the "OPLA"), Ohio Rev. Code §§ 2307.71–.80. These five claims are for: (1) manufacturing defect, § 2307.74;[3] (2) design defect, § 2307.75; (3) inadequate warning, § 2307.76; (4) nonconformance with manufacturer representations, § 2307.77; and (5) supplier liability for negligent misrepresentation, § 2307.78. (Doc. 7-1, PgID. 68–74, 77–79).

Plaintiffs also bring one claim for breach of express warranty under Ohio Rev. Code § 1302.26. (Doc. 7-1, PgID. 79–81). Plaintiffs rest two further claims, for fraudulent

[3] Plaintiffs do not cite in support of their manufacturing defect claim the specific section of the OPLA, Ohio Rev. Code § 2307.74, that provides for that claim. (Doc. 7-1, PgID. 68). But a fair reading of the text of the complaint nevertheless makes sufficiently clear that Plaintiffs seek to bring such a claim independent of their design defect claim. (*See id.* ("First *and Second* Claims for Relief – Ohio Product Liability Act – Defective Design *and* Defective Manufacturing/Construction" (emphasis added))); *see also Inner City Contracting, LLC v. Charter Twp. of Northville*, 87 F.4th 743, 756 (6th Cir. 2023) ("The court's duty is to look to the facts and grant the necessary relief as justice requires—not to demand that certain citations or phrases are used." (quoting *Knapp v. City of Columbus*, 93 F. App'x 718, 720 (6th Cir. 2004))).

misrepresentation and fraudulent concealment, on Ohio common law. (*Id.* at PgID. 74–77). And lastly, Plaintiffs bring a loss of consortium claim on behalf of Plaintiff Phebe Shawver's spouse, Plaintiff Allison Shawver. (Doc. 7-1, PgID. 81).

Legal Standard

Under Federal Rule of Civil Procedure 12(b)(6), I decide whether Plaintiffs' complaint contains "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A complaint need only contain a "short and plain statement of the claim showing that the pleader is entitled to relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 677–78 (2009) (quoting Fed. R. Civ. P. 8(a)(2)). This statement must contain "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 678. I "must construe the complaint in the light most favorable to the plaintiff and accept all [factual] allegations as true." *Doe v. Miami Univ.*, 882 F.3d 579, 588 (6th Cir. 2018) (quoting *Keys v. Humana, Inc.*, 684 F.3d 605, 608 (6th Cir. 2012)).

Discussion

In its motion, Defendant offers two primary arguments for dismissing Plaintiffs' claims. First, Defendant argues that the OPLA abrogates those of Plaintiffs' claims not premised on specific provisions of that statute. (Doc. 9, PgID. 98–101). Defendant then argues that the MDA preempt Plaintiffs' remaining OPLA claims. (*Id.* at PgID. 101–06).[4]

1. OPLA Abrogation

In a 2005 amendment to the OPLA, the Ohio legislature revised the statute to express explicitly the legislature's intent that the OPLA "abrogate all common law product liability

[4] Defendant also makes several arguments in the alternative. (*E.g.*, Doc. 9, PgID. 109–10 (arguing that Plaintiffs' fraud-related claims fail to meet Rule 9(b)'s heightened pleading standard)). I also address those arguments where relevant.

claims or causes of action." Ohio Rev. Code § 2307.71(B). The OPLA defines a "product liability claim" as:

> A claim or cause of action that is asserted in a civil action pursuant to sections 2307.71 to 2307.80 of the Revised Code and that seeks to recover compensatory damages from a manufacturer or supplier for death, physical injury to person, emotional distress, or physical damage to property other than the product in question, that allegedly arose from any of the following:
>
> (a) The design, formulation, production, construction, creation, assembly, rebuilding, testing, or marketing of that product;
>
> (b) Any warning or instruction, or lack of warning or instruction, associated with that product;
>
> (c) Any failure of that product to conform to any relevant representation or warranty.

Ohio Rev. Code § 2307.71(A)(13).[5]

Defendants argue that the OPLA therefore abrogates Plaintiffs' claims for fraudulent misrepresentation and fraudulent concealment. (Doc. 9, PgID. 99–100).[6]

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[5] As noted, part of the statutory definition for a "product liability claim" includes "a claim or cause of action that is asserted in a civil action pursuant to sections 2307.71 to 2307.80 of the [Ohio] Revised Code." Ohio Rev. Code § 2307.71(A)(13). In light of this provision, one might arguably conclude that the OPLA's various provisions reach only those claims brought pursuant to that statute. But I agree with the well-reasoned view of my colleague that such a reading of the statute is unsound. *Miles v. Raymond Corp.*, 612 F. Supp. 2d 913, 921 (N.D. Ohio 2009) (Lioi, J.). As now Chief Judge Lioi explained:

> Under Ohio law it is the substance of the claim, not the manner in which it is pleaded, that determines how it is treated. Applying the portion of the definition [in the manner suggested] would render § 2307.71(B) completely meaningless, as a product liability claim asserted pursuant to statute cannot, by definition, be a "common law" cause of action. Principles of statutory interpretation require that the Court give meaning to all the words in the statute whenever possible and to strictly avoid any interpretation that renders a provision meaningless or inoperative. Construing the statute in the manner suggested [] would run afoul of both of these edicts, a result this Court cannot sanction.

Id. (citations omitted).

[6] Defendants also argue that the OPLA abrogates Plaintiffs' claim for breach of express warranty. (Doc. 9, PgID 101). But because Plaintiffs ground that claim in Ohio Rev. Code § 1302.26, that claim is not a "common law" claim subject to OPLA abrogation. *CCB Ohio LLC v. Chemque, Inc.*, 649 F. Supp. 2d 757, 763 (S.D. Ohio 2009) (citing Ohio Rev. Code § 1302.26 in support of the proposition that "Plaintiffs' warranty claims can find a basis grounded in the Uniform Commercial Code [UCC] and therefore are not claims abrograted [sic] by the OPLA"); *see Miles*, 612 F. Supp. 2d at 923–27 (analyzing whether the OPLA abrogates common law express warranty claims, emphasizing that the court's analysis does not reach "UCC-based claims," and separately analyzing the viability of such UCC-based claims "under contract law and Ohio Revised Code § 1302.26 *et seq*").

In response, Plaintiffs argue without citation to any authority or further explication that because "[t]he duty not to deceive is distinct from the duty to warn," the OPLA's abrogation provision does not reach Plaintiffs' fraudulent misrepresentation and fraudulent concealment claims. (Doc. 7-1, PgID. 74; Doc. 10, PgID. 147).

As an initial matter, Plaintiffs do not dispute Defendant's characterization of these claims as "common law" claims under the OPLA. And both claims arise out of Defendant's alleged "warning or instruction, or lack of warning or instruction," regarding the Mobi-C implant. Ohio Rev. Code § 2307.71(A)(13)(b) (defining a "product liability claim" under the OPLA); (*e.g.*, Doc. 7-1, PgID. 75 ("Despite the fact that Defendant knew, or should have known, the Implant posed a serious risk of bodily harm to patients, Defendant continued to manufacture and market the Implant for implantation into patients without revising any warning language or issuing a recall.")). Plaintiffs' fraudulent misrepresentation and fraudulent concealment claims are therefore "common law product liability claims" for purposes of the OPLA's abrogation provision. Ohio Rev. Code § 2307.71(B); *see Stratford v. SmithKline Beecham Corp.*, No. 07-cv-639, 2008 WL 2491965, at *5 (S.D. Ohio June 17, 2008) (concluding that the OPLA preempted the plaintiff's negligence claim because "[t]he actionable conduct that form[ed] the basis of the negligence claim—negligent research, manufacturing, testing, marketing, and failure to warn—is the same conduct that the OPLA defines as giving rise to a 'products liability claim'").

Courts in this district and elsewhere have recognized, however, that "claims of active misrepresentation are not necessarily abrogated by the OPLA because they may implicate the

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Of course, a plaintiff must put a defendant on notice as to the specific nature of her breach of warranty claim. *See Miller v. ALZA Corp.*, 759 F. Supp. 2d 929, 943–44 (S.D. Ohio 2010) (granting summary judgement for the defendants regarding the plaintiff's breach of warranty claims because "nothing in Plaintiff's Complaint indicates that the warranty claims are being pursued under O.R.C. Chapter 1302"). Here, however, Plaintiffs did cite to Ohio Rev. Code § 1302.26 in their complaint. (Doc. 7-1, PgID. 79).

Nevertheless, although the OPLA does not abrogate Plaintiffs' statutory breach of express warranty claim, I dismiss that claim without prejudice for different reasons further discussed below.

more general duty not to deceive, rather than the duty to warn." *Stratford*, 2008 WL 2491965, at *8; *Kelley v. Insys Therapeutics, Inc.*, No. 18-cv-1774, 2019 WL 329600, at *5–6 (N.D. Ohio Jan. 25, 2019) (Carr, J.) ("Courts in this circuit have held that [fraud and misrepresentation] claims are viable where they are 'based on a general duty not to actively deceive.'" (quoting *Hogue v. Pfizer, Inc.*, 893 F. Supp. 2d 914, 918 (S.D. Ohio 2012))); *Elward v. Electrolux Home Prods., Inc.*, 264 F. Supp. 3d 877, 896 (N.D. Ill. 2017) ("In ascertaining whether a claim is abrogated by the OPLA, courts have differentiated claims based on the defendant's negligent failure to warn from those based on the defendant's general duty not to deceive, holding that only the former are abrogated by the OPLA.").

Whether a plaintiff's claim indeed implicates a defendant's general duty not to deceive, however, is a nuanced inquiry requiring a careful parsing of the complaint. *See Kelley*, 2019 WL 329600, at *6 ("At least two courts in this Circuit have held that the OPLA abrogated claims alleging affirmative misrepresentations where the claims were based upon a duty to warn." (internal quotations omitted)). Courts have held that, where a plaintiff's allegations of active misrepresentation ultimately stem from the defendant's allegedly inadequate warnings, the OPLA abrogates the plaintiff's related fraud claims. *See Johnson v. Eli Lilly & Co.*, No. 14-cv-453, 2015 WL 1120009, at *2 (S.D. Ohio Mar. 12, 2015) ("Plaintiff alleges that instead of disclosing [the drug's] risks, Defendant made consistent and repeated misrepresentations in its promotional materials and marketing documents . . . . These allegations show that Plaintiff's fraud claim is based on a theory of omission and concealment." (internal citations and quotations omitted)); *Hendricks v. Pharmacia Corp.*, No. 12-cv-00613, 2014 WL 2515478, at *4 (S.D. Ohio June 4, 2014) ("[Plaintiff's] contention that Defendants actively misrepresented the safety

of [their drug] presents a closer case for active fraud. Plaintiff's allegation, however, still falls under a failure to warn theory.").

Here, many of the allegations supporting Plaintiffs' two fraud-based claims sound in theories of failure to warn, omission, and concealment that the OPLA abrogates.[7] For example, Plaintiffs allege that "[d]espite the fact that Defendant knew, or should have known, the Implant posed a serious risk of bodily harm to patients, Defendant continued to manufacture and market the Implant for implantation into patients without revising any warning language or issuing a recall." (Doc. 7-1, PgID. 75). And Plaintiffs claim that "Defendant failed to advise physicians and patients of the need for regular follow-up as to properly detect failure of the Implant to prevent or at least minimize related injuries." (*Id.*). Plaintiffs also assert that "Defendant specifically failed to disclose the Implant's propensity to undergo component loosening and other failure causing serious complications including injuries and the need for further surgery in patients . . . ." (*Id.* at PgID. 76). The OPLA abrogates fraud-related claims resting on these sorts of allegations. Therefore, to the extent the OPLA abrogates Plaintiffs' fraud claims, I dismiss those claims with prejudice.

Plaintiffs also allege, however, that "[s]ince the Implant's approval and on multiple occasions through the present, Defendant has fraudulently misrepresented information regarding the character, safety, quality and/or effectiveness of its product." (*Id.* at PgID. 74). Construing the complaint in the light most favorable to the Plaintiffs, as I must at this stage, I conclude that the OPLA does not necessarily abrogate this sort of fraud claim, which might relate to instances of active misrepresentation. *See, e.g.*, *Gordon v. B. Braun Med. Inc.*, No. 19-cv-121, 2020 WL

[7] Because Plaintiffs in their complaint do not distinguish between those allegations that support their claim of fraudulent concealment and those that support their claim of fraudulent misrepresentation, I analyze the two claims together here.

1491378, at *10 (S.D. Ohio Mar. 27, 2020) ("Plaintiff's fraudulent misrepresentation claim is not precluded by OPLA to the extent Plaintiff alleges active misrepresentation.").

But such fraud claims must still meet the heightened pleading standard for fraud set in Federal Rule of Civil Procedure 9(b). That Rule requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Among other details, a plaintiff must "allege the time, place, and content of the alleged misrepresentation on which he or she relied." *DBI Invs., LLC v. Blavin*, 617 F. App'x 374, 384 (6th Cir. 2015) (quoting *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 342 F.3d 634, 643 (6th Cir. 2003)).

Plaintiffs' fraud claims here lack such necessary details. I therefore dismiss without prejudice Plaintiffs' fraud claims to the extent those claims allege Defendant's active misrepresentation.[8]

2. MDA Preemption

Defendant next argues that the MDA expressly preempt most of Plaintiffs' remaining claims. (Doc. 9, PgID. 101–06). These claims include Plaintiffs' claims for defective design, defective manufacturing, failure to warn, nonconformity with manufacturer representation, and

[8] My dismissal of a claim in this order "without prejudice" is a dismissal without prejudice to the filing of an amended complaint. *Cf. Empire Title Servs., Inc. v. Fifth Third Mortg. Co.*, 298 F.R.D. 528, 530 (N.D. Ohio 2014) (Pearson, J.) ("[C]ourts have recognized that 'leave to amend is particularly appropriate where the complaint does not allege fraud with particularity.'" (quoting *Morse v. McWhorter*, 290 F.3d 795, 800 (6th Cir. 2002))).

Also, I do not decide in this order the further question of whether federal law might preempt Plaintiffs' adequately alleged claims of active fraudulent misrepresentation. *See Riegel*, 552 U.S. at 330 (holding that the MDA preempt state law claims that impose liability for a medical device "notwithstanding [that device's] compliance with the relevant federal requirements"); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001) (holding that "the plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law").

negligent misrepresentation under the OPLA. (*Id.*). They also include Plaintiffs' claim for breach of warranty under Ohio Rev. Code § 1302.26. (*Id.*).[9]

The MDA's express preemption provision states in relevant part that:

> No State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

In *Riegel v. Medtronic, Inc.*, the Supreme Court considered the effect of this provision on the viability of certain state law claims brought against the manufacturer of a Class III medical device that had received FDA premarket approval. 552 U.S. 312, 315–21 (2008). The Supreme Court concluded that these claims reflected state tort duties constituting the sort of state law "requirements" that Congress sought to preempt through the MDA's express preemption provision. *Id.* at 323–25.

In reaching that conclusion, the Supreme Court also established a two-part test for determining whether the MDA preempt a plaintiff's state law claim:

> First, "[I] must determine whether the Federal Government has established requirements applicable to [the device at issue]." If

[9] Plaintiffs argue that because preemption is an affirmative defense, a Rule 12(b)(6) motion "is not the appropriate vehicle for a preemption challenge." (Doc. 10, PgID. 142). Admittedly, "[c]ourts generally cannot grant motions to dismiss on the basis of an affirmative defense unless the plaintiff has anticipated the defense and explicitly addressed it in the pleadings." *Princeton Excess & Surplus Lines Ins. Co. v. Caraballo*, 693 F. Supp. 3d 783, 790 (N.D. Ohio 2023) (Barker, J.) (quoting *Est. of Barney v. PNC Bank, Nat'l Ass'n*, 714 F.3d 920, 926 (6th Cir. 2013)). But "[t]here is no reason not to grant a motion to dismiss where the undisputed facts conclusively establish an affirmative defense as a matter of law." *Est. of Barney*, 714 F.3d at 926 (quoting *Hensley Mfg., Inc. v. ProPride, Inc.*, 579 F.3d 603, 613 (6th Cir. 2009)).

Here, the parties do not dispute that the Mobi-C implant is a Class III medical device with FDA premarket approval. And as I discussed above, *supra* note 2, I may take judicial notice of this fact on a motion to dismiss. Because this undisputed, judicially noticed fact is the only fact on which Defendant rests its preemption argument, I may reach that argument in deciding Defendant's motion to dismiss.

> so, then I must determine whether the state law claims impose "requirements with respect to the device that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness."

Warstler v. Medtronic, Inc., 238 F. Supp. 3d 978, 986 (N.D. Ohio 2017) (Carr, J.) (quoting *Riegel*, 552 U.S. at 321–22).[10]

But the Supreme Court in *Riegel* did not entirely foreclose state law product liability claims against Class III medical device manufacturers with FDA premarket approval. Instead, the Court held that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)). Thus, for example, the MDA does not preempt state law product liability claims premised on a defendant's alleged violation of specific FDA manufacturing regulations. *See Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x 436, 439–41 (6th Cir. 2010) (permitting the plaintiff's state law negligence claim to proceed where he "identif[ied] a specific [FDA regulation] that he thought had been violated" and where "the particular [regulation] that he cites is not so vague as to be incapable of enforcement"); *Kodger v. Zimmer Biomet Holdings, Inc.*, No. 17-cv-1350, 2017 WL 4348997, at *3–5 (N.D. Ohio Sept. 29, 2017) (Gwin, J.) (permitting the plaintiff's state law negligence and strict liability claims to

[10] The Supreme Court's opinion in *Riegel* focused on the effect of the MDA's express preemption provision on state common law claims, not claims premised on a state statute. *See Riegel*, 552 U.S. at 324–25 ("[I]n the context of this legislation excluding common-law duties from the scope of pre-emption would make little sense."). But the opinion's reasoning seems to imply that the MDA's express preemption provision would also reach claims authorized by statute like those at issue here. *See id.* at 325 ("State tort law that requires a manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect."); *see also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 489 (1996) (plurality opinion) ("[W]hen Congress enacted § 360k, it was primarily concerned with the problem of specific, conflicting state statutes and regulations rather than the general duties enforced by common-law actions.").

In any event, neither party argues that the underlying statutory basis for most of Plaintiffs' claims is a distinction with a difference under *Riegel*. Indeed, these claims implicate the same sort of preemption issues as those discussed in *Riegel*. I therefore conclude that the same sort of preemption analysis applied in *Riegel* fits here.

proceed where the plaintiff "has alleged Defendants' violations of specific [FDA] manufacturing requirements").

Here, the parties do not dispute that Defendant's Mobi-C implant is a Class III device that received FDA premarket approval. The FDA has therefore "established requirements applicable to" the device. *Riegel*, 552 U.S. at 321–23 ("Premarket approval . . . imposes 'requirements' under the MDA . . . . [Premarket approval] is in no sense an exemption from federal safety review—it *is* federal safety review.").

The next question, then, is whether Plaintiffs' remaining claims, which all relate to the safety or effectiveness of the Mobi-C implant, impose requirements "different from, or in addition to," the FDA's requirements. 21 U.S.C. § 360k(a)(1).

First, Ohio Rev. Code § 2307.74 requires that Plaintiffs' manufacturing defect claim allege how the Mobi-C implant "deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards." Ohio Rev. Code § 2307.74. Plaintiffs' complaint, however, simply never identifies the nature of Defendant's alleged deviation.[11]

Plaintiffs insist in their opposition briefing that "[d]iscovery will uncover further details of the device failure." (Doc. 10, PgID. 143). That may be true, but that does not excuse Plaintiffs' failure to allege any factual support for their defect claim. *E.g.*, *Anderson v. Bos. Sci. Corp.*, No. 12-cv-00762, 2013 WL 632379, at *3 (S.D. Ohio Feb. 20, 2013) ("[D]iscovery

[11] Plaintiffs do allege that the second surgery extracting the device discovered that "the polyethylene spacer [had] failure of one of the posterior phalanges, which was removed along with another fragment." (Doc. 7-1, PgID. 67). But Plaintiffs never explain what manufacturing defect might have caused this failure. And because a medical device might fail for many reasons, the device's alleged failure cannot by itself support a reasonable inference of manufacturing defect.

cannot be used as a fishing expedition to uncover the facts necessary to support the causes of action presented in the complaint, 'even when the information needed to establish a claim . . . is solely within the purview of the defendant or a third party.'" (quoting *New Albany Tractor, Inc. v. Louisville Tractor, Inc.*, 650 F.3d 1046, 1051 (6th Cir. 2011))). Because Plaintiffs fail to allege sufficient "factual content that allows the court to draw the reasonable inference" that a manufacturing defect existed, *Iqbal*, 556 U.S. at 678, I will dismiss Plaintiffs' manufacturing defect claim without prejudice.[12]

Next, Plaintiffs' design defect claim under Ohio Rev. Code § 2307.75 requires Plaintiffs to show that "the foreseeable risks associated with [the Mobi-C implant's] design or formulation . . . exceeded the benefits associated with that design or formulation." Ohio Rev. Code § 2307.75(A). But the Mobi-C implant received the FDA's premarket approval, a process requiring the FDA to conduct its own risk-benefit analysis. *See* 21 U.S.C. § 360c(a)(2)(C) ("[T]he safety and effectiveness of a device are to be determined . . . weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use."). Thus, Plaintiffs' design defect claim constitutes "a frontal 'attack[ ] on the risk/benefit analysis that led the FDA to approve' the device." *Aaron v. Medtronic, Inc.*, 209 F. Supp. 3d 994, 1007 (S.D. Ohio 2016) (quoting *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1206 (8th Cir. 2010)).

In their opposition briefing, Plaintiffs attempt to characterize their complaint as a broad claim that "Defendant was *not* compliant with the relevant federal requirements." (Doc. 10,

[12] As with Plaintiffs' fraud claims discussed above, *supra* note 8, I do not decide in this order the further question of whether federal law might preempt Plaintiffs' adequately alleged claim of manufacturing defect. *See Warstler*, 238 F. Supp. 3d at 987 (concluding that the MDA preempted plaintiff's claim of manufacturing defect in part because "there [was] no allegation that defendant did not produce plaintiff's [] device according to FDA specifications *per* the PMA").

PgID. 150). Regarding their design defect claim, Plaintiffs emphasize that their claim would merely parallel federal requirements "if Defendant changed the design of the Device" to deviate from those requirements. (*Id.*). Perhaps that proposition is correct. But I need not decide that question because Plaintiffs nowhere allege in their complaint that Defendant engaged in such conduct. I therefore conclude that the MDA preempt Plaintiffs' design defect claim as pleaded and will dismiss that claim without prejudice.

Plaintiffs' failure to warn claim under Ohio Rev. Code § 2307.76 is deficient for similar reasons. That statute provides in relevant part for a manufacturer's liability when the manufacturer "failed to provide the warning or instruction that a manufacturer exercising reasonable care would have provided" regarding a risk of which the manufacturer was or should have been aware. Ohio Rev. Code § 2307.76(A)(1); *see also* § 2307.76(A)(2) (providing for similar liability in a post-marketing context).

Here, Plaintiffs make a variety of related allegations regarding Defendant's failure to warn. For example, Plaintiffs allege that "Defendant failed to timely and reasonably warn of material facts regarding the comparative safety and efficacy of the [Mobi-C] Implant" and "failed to perform or otherwise facilitate adequate testing." (Doc. 7-1, PgID. 72). Plaintiffs also assert that Defendant "failed to provide adequate warning for consumers of the Implant of its enhanced risk compared to other options." (*Id.* at PgID. 70).

The MDA plainly preempt Plaintiffs' failure to warn claim to the extent that claim might require warnings "different from, or in addition to," those that the FDA requires through its premarket approval of the Mobi-C implant. 21 U.S.C. § 360k(a)(1). Plaintiffs seek to avoid this problem in much the same way they sought to avoid it regarding their design defect claim. Plaintiffs speculate that, if premised on "[c]hanging the label from the approved FDA label

(without proper approval)," Plaintiffs' failure to warn claim would be a parallel claim. (Doc. 10, PgID. 150). Again, however, even if this proposition is correct, Plaintiffs failed to make such an allegation in their complaint. I therefore again conclude that the MDA preempt Plaintiffs' failure to warn claim as pleaded and dismiss that claim without prejudice.[13]

I now turn to Plaintiffs' claims for nonconformance with manufacturer representations under Ohio Rev. Code § 2307.77 and for breach of express warranty under Ohio Rev. Code § 1302.26.[14]

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[13] I note that curing this deficiency and that regarding Plaintiffs' design defect claim is no idle task. A plaintiff must offer more than generalized allegations of noncompliance like those that Plaintiffs suggested in their opposition briefing. In particular, a plaintiff must identify the specific federal requirements allegedly violated. *Warstler*, 238 F. Supp. 3d at 985 ("[C]ourts have held that parallel claims must be specifically stated in the initial pleadings. A plaintiff must allege that the defendant violated a particular federal specification referring to the device at issue." (internal quotations and alterations omitted)); *see, e.g.*, *Howard*, 382 F. App'x at 440 (permitting the plaintiff's negligence per se claim based on a manufacturing defect to proceed in part because the plaintiff "identif[ied] a specific [regulation] that he thought had been violated"); *Schmidt v. Bos. Sci. Corp.*, No. 15-cv-00488, 2016 WL 1274824, at *3 (N.D. Ohio Mar. 31, 2016) (Adams, J.) (concluding that the plaintiff failed to adequately plead parallel claims because the plaintiff "does not identify the specific FDA requirement that is alleged to have been violated or the specific, parallel Ohio requirement"); *Johnson v. Eli Lilly & Co.*, No. 14-cv-453, 2015 WL 1120009, at *3 (S.D. Ohio Mar. 12, 2015) (concluding that the plaintiff failed to state a manufacturing defect claim where the plaintiff "merely alleged that the [drug] was not made in accordance with Defendant's specifications or performance standards[] and [that] Defendant sold and/or distributed [the drug] in a condition that posed unreasonable risks from reasonably anticipated use" (quotations omitted)); *Friedman v. Intervet Inc.*, No. 09-cv-2945, 2010 WL 2817257, at *3 (N.D. Ohio July 16, 2010) (Carr, J.) (permitting the plaintiff's manufacturing defect claim to proceed where the plaintiff alleged "that test results showed the product was out of specification with regard to its primary compound, and that this was a deviation from the product's intended characteristics").

[14] When identifying their breach of express warranty claim in their complaint, Plaintiffs also provide a citation to Ohio Rev. Code § 1302.28. That statute provides that "[w]here the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is . . . an implied warranty that the goods shall be fit for such purpose." Ohio Rev. Code § 1302.28.

But the text of the complaint suggests Plaintiffs seek to bring only one claim in this section. (*See* Doc. 7-1, PgID. 79 ("Eighth Claim for Relief – Breach of Express Warranty for Particular Purpose")). This section of the complaint also discusses only Defendant's alleged express warranties. (*E.g.*, *id.* at PgID. 79–80 ("99. Defendant expressly warranted the Implant as a safe and effective orthopaedic [sic] Implant. 100. The express warranties made by Defendant were an element of the basis for the reliance of Plaintiff Phebe Shawver and her physician in deciding to use the Implant.")).

Even construing Plaintiffs' complaint as intending to assert a tenth claim against Defendants for breach of an implied warranty, the lack of any supporting allegations beyond a citation to the relevant Ohio statute requires me to dismiss the claim without prejudice. *See Freeman v. Tenn. Dep't of Corr.*, 22-cv-00963, 2023 WL 4378098, at *2 (M.D. Tenn. July 6, 2023) ("[T]he mere citation of this statute is not sufficient to support a plausible claim to relief based on the de minimis deprivation described in the complaint.").

Plaintiffs also attempt to assert a breach of implied warranty claim through Ohio Rev. Code § 2307.77 (nonconformance with manufacturer representations). That statute, however, defines "representation" as "an *express* representation of a material fact concerning the character, quality, or safety of a product." Ohio Rev. Code §

Plaintiffs' nonconformance with manufacturer representation claim alleges that "Defendant expressly . . . warranted that the Implant was safe and fit for use by patients, that it was of merchantable quality, that its risks were minimal and comparable to other cervical disc systems, and that it was adequately tested and fit for its intended use." (Doc. 7-1, PgID. 73). Plaintiffs' breach of express warranty claim alleges that "Defendant expressly warranted the Implant as a safe and effective orthopaedic [sic] Implant." (*Id.* at PgID. 79).

Courts in this circuit have recognized that breach of warranty claims may avoid preemption under the MDA where they allege related violations of federal requirements. For example, in *Hawkins v. Medtronic, Inc.*, 909 F. Supp. 2d 901 (S.D. Ohio 2012), the court allowed the plaintiff's breach of implied warranty claim to proceed because "it is clear from the allegations that Plaintiff's claim is in fact premised on the theory that Defendant violated federal law." *Id.* at 911; *see also Thorn v. Medtronic Sofamor Danek, USA, Inc.*, 81 F. Supp. 3d 619, 630 (W.D. Mich. 2015) (concluding that "an adequately pleaded claim for breach of express warranty is not expressly preempted [because] [f]ederal law 'already requires [the defendant] to ensure that any warranty statements it voluntarily makes are truthful, accurate, not misleading, and consistent with applicable federal and state law'" (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 788 (D. Minn. 2009))).

Courts in this circuit and elsewhere have also recognized that breach of warranty claims may avoid preemption where they rest on the defendant's voluntary statements made separately from the FDA's regulatory process. *See Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844, 863 (W.D. Tenn. 2015) ("To the extent that Plaintiffs claim warranties voluntarily made to individual Plaintiffs, such a claim would not be preempted."); *see also Houston v. Medtronic, Inc.*, 957 F.

2307.71(14) (emphasis added). To the extent Plaintiffs attempt to allege breach of implied warranty claims through § 2307.77, I dismiss those claims with prejudice.

Supp. 2d 1166, 1181 (C.D. Cal. 2013) ("[T]o the extent that Plaintiff seeks to impose liability on Defendants for voluntarily making misleading warranties outside the label, Plaintiff is not imposing any requirement different from or additional to what federal law already requires.").

The devil, as always, is in the details. But here, Plaintiffs fail to allege any of the necessary details. The broad, generalized allegations in the complaint regarding Defendant's alleged warranties simply provide no basis from which I can reasonably infer whether they are the type of warranty claims that might survive MDA preemption. Plaintiffs do not describe "in any fashion what the express warranty made by Defendant[] was and how that express warranty could be enforced by Ohio law in a parallel fashion to federal law." *Aaron*, 209 F. Supp. 3d at 1008. I therefore dismiss Plaintiffs' claims under Ohio Rev. Code § 2307.77 and § 1302.26 without prejudice.[15]

Plaintiffs' penultimate claim is for negligent misrepresentation under Ohio Rev. Code § 2307.78. As an initial matter, the statute limits liability to a "supplier," which "does not include . . . [a] manufacturer." Ohio Rev. Code § 2307.71(A)(15)(b)(i). Throughout their complaint, Plaintiffs claim, for example, that Defendant "developed, designed, tested, manufactured, distributed, marketed, and/or sold" the Mobi-C implant. (*E.g.*, Doc. 7-1, PgID. 66). Of course, to the extent a factfinder might find Defendant liable for defective manufacturing, for example,

[15] In a footnote in their complaint, Plaintiffs provide a citation to an online article titled "Cervical Artificial Disc Replacement Outcomes at 5 to 10 Years." (Doc. 7-1, PgID. 80). Plaintiffs offer this citation as support for their allegation that "[t]he [Mobi-C] Implant does not conform to [Defendant's] express representations, as evidenced by the fact that Plaintiff Phebe Shawver's implant failed prematurely." (*Id.*). Perhaps Plaintiffs' cited article properly serves as evidence that Plaintiff's implant failed prematurely. But that article's reference in an unadorned footnote lacking further explication sheds no light on what specific warranties Defendant might have made regarding the Mobi-C implant.

Furthermore, in their opposition briefing, Plaintiffs quote what they identify as an express warranty from Defendant regarding the Mobi-C implant's superiority over "fusion" as a treatment option. (Doc. 10, PgID. 152). They source this quote to a webpage that appears inoperable. (*Id.*). Even if this alleged warranty might be relevant here, Plaintiffs' opposition briefing is not a pleading. *See* Fed. R. Civ. P. 7(a). And because I generally may not consider matters outside the pleadings on a Rule 12(b)(6) motion to dismiss, *see* Rule 12(d), I decline to consider this alleged express warranty here.

Defendant could not also face supplier liability under § 2307.78. But "at this early stage, Plaintiff[s are] permitted to cover [their] bases and plead in the alternative that Defendants are liable as suppliers." *Gordon*, 2020 WL 1491378, at *6.

But once again, Plaintiffs' allegations are far too general to survive preemption under the MDA. For example, Plaintiffs claim Defendant's misrepresentations included "assurances that the Implant was safe, had an excellent performance record and did not have a greater propensity to undergo component loosening and/or other failure." (Doc. 7-1, PgID. 78). To the extent Plaintiffs' claim asserts that Defendant "violated state [] law notwithstanding compliance with the relevant federal requirements," the MDA preempt their claim. *Riegel*, 552 U.S. at 330. These allegations afford me no basis from which I can reasonably infer that Plaintiffs' negligent misrepresentation claim merely parallels federal requirements. I therefore dismiss this claim without prejudice.[16]

Finally, I briefly turn to Plaintiffs' loss of consortium claim. "Under Ohio law, 'a claim for loss of consortium is derivative in that the claim is dependent upon the defendant's having committed a legally cognizable tort upon the spouse who suffers bodily injury.'" *Smith v. Hartz*

[16] In its motion to dismiss, Defendant argues that Rule 9(b)'s heightened pleading standard for claims of "fraud or mistake" applies to Plaintiffs' claim of negligent misrepresentation. (Doc. 9, PgID. 109–10). This issue "has divided numerous courts of appeals." *Casey v. Wright Med. Tech., Inc.*, No. cv-19-05360, 2020 WL 736306, at *4 (D. Ariz. Feb. 13, 2020) (summarizing conflicting caselaw regarding whether Rule 9(b) applies to the pleading of negligent misrepresentation claims).

Nevertheless, I do not think this question is relevant in this case. How a plaintiff chooses to label her complaint sheds dim light, if any at all, on the substance of her complaint's claims. *See Minger v. Green*, 239 F.3d 793, 799 (6th Cir. 2001) ("[T]he Rules require that we not rely solely on labels in a complaint, but that we probe deeper and examine the substance of the complaint. . . . '[T]he label which a plaintiff applies to a pleading does not determine the nature of the cause of action which he states.'" (quoting *United States v. Louisville & Nashville R.R. Co.*, 221 F.2d 698, 701 (6th Cir. 1955))).

Here, Ohio Rev. Code § 2307.78(A)(2) makes clear that a supplier is liable for a nonconforming representation "even though the supplier did not act fraudulently, recklessly, or negligently in making the representation." *Id.* Thus, the allegations of fraud or mistake that trigger Rule 9(b)'s heightened pleading requirement play no role in the substance of claims under this provision. I therefore decline both: (1) to decide whether Rule 9(b) might apply to negligent misrepresentation claims generally; and (2) to apply Rule 9(b) to Plaintiffs' Ohio Rev. Code § 2307.78 claim here.

Mountain Corp., No. 12-cv-00662, 2012 WL 5451726, at *5 (N.D. Ohio Nov. 7, 2012) (Helmick, J.) (quoting *Bowen v. Kil-Kare, Inc.*, 585 N.E.2d 384, 392 (Ohio 1992)). Because I dismiss Plaintiffs' underlying claims without prejudice, I must also dismiss Plaintiffs' loss of consortium claim without prejudice.

Conclusion

For the foregoing reasons, it is ORDERED THAT:

1. Defendant's motion to dismiss (Doc. 9) be, and the same hereby is, granted;
2. Plaintiffs' claims are dismissed without prejudice to the filing of an amended complaint, except for the following claims that I dismiss with prejudice: (1) Plaintiffs' fraud-related claims to the extent the OPLA abrogates those claims as discussed in this order; and (2) Plaintiffs' claim for breach of implied warranty under Ohio Rev. Code § 2307.77; and
3. Plaintiffs may file an amended complaint within three weeks of issuance of this order. Failure to file an amended complaint within that timeframe will result in the filing of a final judgment on the merits.

SO ORDERED.

DATE: 10/10/2024

/s/ James G. Carr

Sr. U.S. District Judge